PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	09.09.2005
Applicant's or agent's file reference	IMPORTANT NOTIFICATION
041748wo HPJ	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/007215	02.07.2004	03.07.2003

Applicant
B. BRAUN MEDICAL AG et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 041748wo HPJ	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/007215	International filing date *(day/month/year)* 02.07.2004	Priority date *(day/month/year)* 03.07.2003
International Patent Classification (IPC) or national classification and IPC B32B27/08, B32B27/30, B32B27/32, B32B27/36, A61J1/00		
Applicant B. BRAUN MEDICAL AG et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.05.2005	09.09.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Seiberlich, P Telephone No. +49 89 2399-8663

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/007215

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-20	as originally filed
Claims, Numbers	
1-15	received on 23.08.2005 with letter of 22.08.2005
Drawings, Sheets	
1/4-4/4	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-15
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following document/s (D) is/are referred to in this communication:

D1: EP-A-0 774 348 (BRAUN MELSUNGEN AG)

1. Novelty

Document D1, which is considered to represent the most relevant state of the art, discloses sterilisable co-extruded films for wrapping containers for solutions, suspensions, solids or mixtures for parenteral, enteral or stomach tube feeding.
The tube consists of three layers, i.e.
(a) polypropylene homopolymer (homo-PP, outer layer),
(b) ethylene vinylalcohol copolymer (EVOH), in particular a copolymer with an ethylene content of 27-38 mole% and
(c) a single-phase PP homo- or co-polymer (inner layer).
The three layers (a), (b) and (c) have thicknesses of 20-40 μm (a), 15-35 μm (b) and 30-50 μm, respectively; cf. D1, the passages cited in the Search Report, in particular the claims. The material of inner layer (b) is selected to provide the required oxygen barrier properties. It is clear that the ethylene content of the EVOH copolymer is selected to maintain barrier properties during sterilization at 121°C (cf. p 2/3, bridging paragraph and p 3/l 11-21 and 37).

The claimed films differ from those according to D1 in the nature of the outer layer (i.e. the presence of a (co)PET outer layer. Thus, the claimed films are novel over the disclosure in D1. The subject-matter of present claims 1-15 therefore appears to meet the requirements of Article 33(2) PCT.

2. Inventive Step

The claimed films differ from the most relevant state of the art (D1) in the nature of their

outer layer and in their desorption properties.
The problem to be solved by the present application may therefore be regarded as to provide multilayer films having a low oxygen transmission rate (i.e. <0.7 ml/m^{2}d) and at the same time allowing for improved recovery of the gas barrier properties of the core layer after sterilization.
It appears from a comparison of the results presented in Fig. 3 that the presence of an outer layer of PET instead of PP renders the obtainable films more effective in the desorption of water and, thus, improves the long term barrier properties of the corresponding container.
None of the documents of the prior art contains an incentive for the skilled person to combine layers of a saponified polyolefin-vinyl acetate copolymer in combination with layers of a polyalkylene terephthalate resin (e.g. bonded by means of an adhesive) when aiming at structures allowing for improved desorption of water e.g. absorbed during sterilization. Thus, the subject-matter of present claims 1, 12 and 13 appears to meet the requirements of Article 33(3) PCT.

Claims 2-11, 14 and 15 are dependent on claim 1 or 13 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

PCT/EP2004/007215 HPJ/RC/cr 3 May 2005
B. Braun Medical AG

Amended Claims:

1. Sterilizable multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents, having a three-layered structure with an inner layer being in contact with the content of the container, an intermediate layer and an outer layer facing the environment, said layers optionally connected by tie and/or adhesive layers, wherein
the oxygen transmission rate at 23 °C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7 ml/m²d,
said inner layer having a thickness of from 30 to 120 µm,
said intermediate layer having a thickness of from 5 to 35 µm and said outer layer having a thickness of from 20 to 40 µm, and
comprising or substantially consisting of polyethylene terephthalate homopolymer and/or polyethylene terephthalate copolymer, and
allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

2. The multilayer film according to claim 1, wherein said oxygen transmission rate at 23 °C is less than 0.4 ml/m²d.

3. The multilayer film according to claim 1 or 2, having an inner layer essentially consisting of non-polar polymeric material.

4. The multilayer film according to claim 3, having an inner layer comprising or substantially consisting of polypropylene homopolymer and/or polypropylene copolymer.

5. The multilayer film according to any one of claims 1 to 4, having an intermediate layer comprising or substantially consisting of ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38, in particular 29 to 32 mol-%.

6. The multilayer film according to any one of claims 1 to 5, characterized in that the multilayer film contains at least one oxygen absorber within one or several of the layers.

7. The multilayer film according to claim 6, wherein said oxygen absorber contains or consists of Fe or Fe(II)-salts.

8. The multilayer film according to claim 6 or 7, wherein said oxygen absorber is contained in said inner layer.

9. The multilayer film according to any one of claims 6 to 8, wherein said oxygen absorber is contained in a tie and/or adhesive layer located between said inner layer and said intermediate layer.

10. The multilayer film according to any one of claims 6 to 9, wherein said oxygen absorber is contained in the respective layer/layers in an amount of 1 to 100 mg/g, particularly 5 to 20 mg/g related to the weight of the respective layer.

11. The multilayer film according to anyone of claims 6 to 10, wherein said oxygen absorber is contained in an amount of 0.5 to 2.0 mg/g related to the overall weight of all layers.

12. Vapor sterilized multilayer film according to any one of claims 1 to 11.

13. Use of the multilayer film according to any one of claims 1 to 12 as a pharma film.

14. Use according to claim 13 to preserve the quality of products for infusion, PVR, dialysis, urology and/or clinical nutrition.

15. Use according to claim 13 or 14 to minimize oxidation and/or adsorption of the ingredients of said products.